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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/692,757 | 10/27/2003 | Israel Yerushalmy | 1131YER-US-CIP | 8858 |

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| EXAMINER | |
|---|---|
| AHMED, AAMER S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3763 | |

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/692,757 | YERUSHALMY, ISRAEL | |
| | Examiner | Art Unit | |
| | Aamer S. Ahmed | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober U.S. Patent number 4,669,477 in view of Njemanze U.S. Patent Number 6,468,219.

Ober discloses an apparatus comprising a biosensor (20) adapted to sense a phenomenon associated with a sleeping disorder event; a stimulating signal applied to a patients jaw to prevent bruxism, a processor (26) in communication with the processor and the signal stimulator (36) for processing signals received from the biosensor and for controlling operation of the signal stimulator, wherein in response to the phenomenon, the biosensor communicates a signal to the processor and the processor operates the stimulating signal module to initiate stimulating signal actuation (see figure 1).

Ober fails to disclose a drug delivery module.

Njemanze discloses a similar device, including injection drug delivery module (col. 5 line 21) containing relaxant.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Ober by incorporating the drug delivery module of the type taught by Njemanze, in order to effectively treat sleep disorders using recognized relaxant drugs.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober U.S. Patent number 4,669,477 in view of Njemanze and further in view of Berthon-Jones et al U.S. Patent Number 5,560,354.

Ober in view of Njemanze disclose the device as described above in reference to claim 1, but fail to explicitly disclose that the device is adapted to emit relaxant to air in the vicinity of the patient.

Berthon-Jones et al discloses a similar device in which the relaxant is emitted to air in the vicinity of the patient (see figure 1b).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Ober in view of Njemanze, by incorporating delivery of the relaxant drug into air in the vicinity of the patient, in order to provide a safe non-invasive delivery device.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober in view of Njemanze and further in view of Reed et al U.S. Patent number 6,299,900.

Ober in view of Njemanze discloses the device as described above in reference to claim 1, but fail to explicitly disclose that the drug module is transdermal.

Reed et al discloses a similar device in which the drug delivery device module comprises a transdermal module (col. 1 line 5).

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Ober in view of Njemanze by incorporating the transdermal drug module of the type taught by Reed et al, in order to provide a safe, non-invasive drug delivery.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim1-6 of prior U.S. Patent No. 6,638,241. This is a double patenting rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6954668 B1 Cuozzo; John W.

US 6632843 B1 Friedman; Mark

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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